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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,144	11/25/2003	Robert J. Ternansky	474930-4 34433/US/3/AMP/S	9257

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 11/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/723,144	TERNANSKY ET AL.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 August 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1, 5, 19-20, 22-43,55-56 and 58-59* is/are pending in the application.

4a) Of the above claim(s) *27-29, 32-33, 40-43* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5,19,20,22-26,30,31,34-39,55,56,58 and 59* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

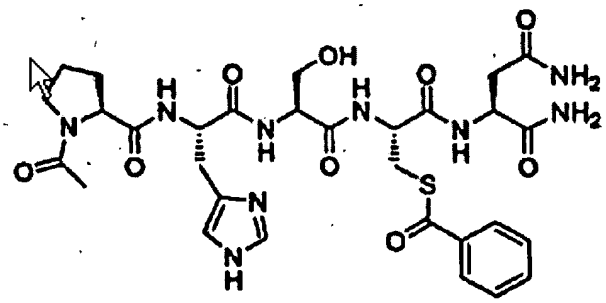
Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/06 and 08/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after allowance or after an Office action under Ex Parte Quayle, 25 USPQ 74, 453 O.G. 213 (Comm'r Pat. 1935). Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on August 18, 2006 has been entered.

Applicants elected the species of Formula I wherein R^1 is acyl (i.e., -$C(O)CH_3$, x is 1, A is Pro, y is 1, B is His, z is 1, C is Ser, a is 1, R^2 is $-(CH_2)_mS(O)_nR^5$, m is 1, n is 0, R^5 is acyl (i.e., C(O)Ph), b is 1, R^3 is $-CH_2CONH_2$, R^4 is $-NR^6R^7$ and R^6 and R^7 are hydrogen, as indicated in the following structure:



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in the reply filed on May 31, 2005 is acknowledged, with claims 1, 5, 19-20, 22, 25, 30-31, 34, 58-59 readable thereon. This species was searched and found to be free of the prior art, however, as drafted, no claims are drawn exclusively to this species. Therefore, Examiner elected a new species (Ac-Pro-His-Ser-Met-Asn-NH_2) from

amongst those encompassed by the instant claims. Claims 1, 5, 19-20, 22-24, 26, 35-39, 55-56, 58-59 are readable thereon and are presented for examination on the merits. Claims 27-29, 32-33, 40-43 are withdrawn as not drawn to either species.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 5, 19-20, 22-26, 30-31, 34-39, 55-56 and 58-59 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Further, 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention (including into the claim language). The added material which is not supported by the original disclosure is as follows:

In claim 1 , at lines 26-27, the removal of the proviso "a is 1 unless A is proline, B is histidine, C is serine and b is 0 when a is 0; and R_2 is $(CH_2)_mS(O)_nR_5$ or $(CH_2)_mS(O)_nS(O)_oR_5$ unless b, x, y and z are 1" is deemed new matter because the instant specification (see pages 3-4), as well as original claim 1 do not properly support the concept of species without that proviso being incorporated within the compounds encompassed by Formula (I). The instant specification (including the original claims)

discloses compounds of Formula (I) with the proviso that "a is 1 unless A is proline, B is histidine, C is serine and b is 0 when a is 0; and R_2 is $(CH_2)_mS(O)_nR_5$ or $(CH_2)_mS(O)_nS(O)_oR_5$ unless b, x, y and z are 1". By removing the limitations stated above, the claims are broadened with no support from the specification. It is suggested that the limitations set forth in the cited claims be appropriately reincorporated into the claims cited above to overcome this rejection.

All other cited claims depend directly or indirectly from rejected claims and are, therefore, also rejected under U.S.C. 112, first paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5, 19-20, 22-24, 26, 35-39, 55-56 and 58-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over Livant (US 6,001,965, citation A19 in the IDS of 08/11/06).

Livant teaches a high activity anti-angiogenic compound Ac-Pro-His-Ser-Cys-Asn-NH_2 (e.g., column 26, 27-40, Figures and Examples 9-13). Livant teaches that substituting the fourth amino acid position for homo-cysteine to produce Ac-Pro-His-Ser-homoCys-Asn-NH_2 (Example 11) maintains a strong inhibitory effect and also teaches that the Cys position may also be occupied by a methionine (e.g., column 3, lines 16-40). Livant does not expressly teach the compound Ac-Pro-His-Ser-Met-Asn-NH_2.
It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the composition Ac-Pro-His-Ser-Cys-Asn-NH_2 of Livant by substituting the cysteine for a methionine as taught by Livant. The skilled artisan would have been motivated to do so because Livant teaches that such amino acid position may be substituted by a methionine (e.g., column 3, lines 16-40). There would have been a reasonable expectation of success, given that the analogous substitution of cysteine for homo-cysteine at that same position produces a strong inhibitory effect (Example 11) and that homo-cysteine and methionine chemically differ only by substitution of a hydrogen for a methyl group. The adjustment of particular conventional working conditions (e.g., selecting specific D/L stereochemistry, e.g., column 3, lines 39-

40) within such compounds is deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan. Thus the invention as a whole was clearly prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 5, 19-20, 22-26, 30-31, 34-39, 55-56 and 58-59 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 64-67 of copending Application No. 10/722,843. The instantly claimed invention and the invention claimed in Application '843 are both drawn to a

genus of compounds which contain overlapping subject matter Further, the instantly claimed broad formula (I) of the instant application encompasses and/or is encompassed by the claimed broad formula (V) of Application '843.

This is a provisional obviousness-type double patenting rejection.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M. Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia J. Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Marcela M Cordero Garcia, Ph.D.
Patent Examiner
Art Unit 1654

MMCG 11/06

11/28/06
ANISH GUPTA
PRIMARY EXAMINER